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EXAMINER	
CLOW, LORI A	

ART UNIT	PAPER NUMBER
1631	

NOTIFICATION DATE	DELIVERY MODE
12/26/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/539,032	BRAHMACHARI ET AL.	
	Examiner	Art Unit	
	Lori A. Clow	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response, filed 3 December 2008, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-4 and 6-9 are currently pending. Claims 5 and 10-12 have been cancelled.

Claim Rejections - 35 USC § 101-Non-statutory Subject Matter

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 and 6-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. This is a new grounds of rejection as necessitated by the recent decision in *In re Bilski.*

Claims 1-4 and 6-9 are drawn to a computer-based method for identifying conserved peptide motifs useful as drug targets for use in a host organism wherein the method comprises steps of computationally generating overlapping peptide sequences, computationally sorting the peptide sequences, computationally matching the sorted peptide sequences, computationally locating the matched common peptide sequences, computationally joining overlapping common peptide sequences, comparing extended conserved peptide sequences and communicating said conserved peptide sequences from said selected pathogenic organisms not present in said host proteins to a user, wherein all of said sequences performed on said computer.

As stated in MPEP 2106, section IV, the claims will be evaluated for providing a practical application, if the claims are found to cover a judicial exception (*i.e.*, Law of Nature, Natural Phenomenon, or an Abstract Idea). This is in line with the recent decision in *In re Bilski* (Federal Circuit, 2008). In the instant case, the claims are drawn to an abstract idea and therefore must be evaluated further for providing a practical application of the judicial exception. A practical application is claimed if the claimed invention physically transforms an article or physical object to a different state or thing, or if the claimed invention otherwise produces a concrete, tangible, and useful result. In the instant case, a physical transformation of matter is not provided, as the instant claims merely provide steps of *in silico* information manipulation. Therefore, none of said steps result in a physical transformation of matter such that the whole of the claim is statutory.

As such, the claims must be further evaluated for providing a practical application. One way to do this is for the claim to produces a concrete, tangible and useful result. The focus is not on the steps taken to achieve a particular result, but rather the final result achieved by the claimed invention. A claim may be statutory where it recites a result that is concrete (i.e. reproducible), tangible (i.e. communicated to a user), and useful (i.e. a specific and substantial). In the instant case the steps of "communicating said conserved peptide sequences from said selected pathogenic organisms not present in said host to a user" does provide a tangible result that is useful to one skilled in the art.

However, in addition to the facts set forth above that state that a claim must provide a practical application, the claim must also meet the machine or transformation test in order to be eligible under 35 USC 101 as statutory subject matter (*In re Bilski*; Federal Circuit, 2008). In

other words, the prohibition on patenting abstract ideas has two distinct aspects: (1) when an abstract concept has no claimed practical application, it is not patentable; (2) while an abstract concept may have a practical application, a claim reciting an algorithm or abstract idea can state statutory subject matter only if it is embodied in, operates on, transforms, or otherwise is tied to another class of statutory subject matter under 35 U.S.C. §101 (i.e. a machine, manufacture, or composition of matter). (*Gottschalk v. Benson*, 409 U.S. 63, 175 USPQ 673, 1972) (*In re Bilski,* Fed. Cir. 2008; machine or transformation test).

In the instant case, claims 1-4 and 6-9 are not so tied to another statutory class of invention because the **method** steps that are critical to the invention are "not limited to any **particular apparatus** or **machinery**" and therefore do not meet the machine or transformation test as set forth in *In re Bilski* (Federal Circuit, 2008). The steps of the instant invention are drawn to abstract ideas and have no utility except to operate on a digital computer, following the logic of *Benson* (409 U.S. at 71-72). Therefore, the tie in the instant claim to a "computer" that is not a specific computer, but rather a general purpose computer, does not reduce the preemptive footprint of the claim because all uses of the abstract idea are still covered by the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 6-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, and claims dependent therefrom, have been amended to recite, "wherein all of said steps are performed on said computer". There is insufficient antecedent basis in the claim for "said computer", as no "computer" was previously recited in the claim. The preamble cites a computer-implemented method however the claim does not recite a computer itself. Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 6-9 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bruccoleri et al. (Nucleic Acids Research (1998) vol. 26, no. 19, pages 4482-4486), for the reasons set forth in the previous Office Action and re-iterated below.

Instant claim 1 is essentially drawn to a computer-based method of identifying conserved peptide motifs useful as drug targets comprising generating overlapping peptide sequences of length N from pathogenic organisms; sorting the peptide sequences to produce matched common peptides; locating matched common peptide sequences in their corresponding protein sequences to gather location and labeling origin and location; joining overlapping common sequences; and comparing extended conserved sequences to a host organism protein sequence to identify which of the conserved peptides are not present in the host.

Bruccoleri et al. teach a method of concordance analysis of microbial genomes in which a set of proteins are computationally analyzed to determine concordance of putative gene products that show sets of proteins conserved across one set of user specified genomes and not present in another set of user specified genomes (abstract). The system uses a relational database to store protein coding regions from different genomes and to store the results of a complete comparison of all sequences against sequences using FASTA. A display, using CLUSTALW can be performed for all related proteins for a given sequence (abstract). Bruccoleri teaches the generation of overlapping sequence alignments from pathogenic organisms (page 4483, Table 3); homolog matching (page 4483, column 1); target sequence CLUSTALW alignment for all sequences (page 4483, column 2); an alignment of just matching gene product against the corresponding gene product in the target; and exclusion criteria. Therefore, Bruccoleri et al. teach the limitations of claim 1.

In regard to claim 2, Bruccoleri teaches a genome of at least 4 (sequence length) (page 4483, Table 3 teaches the *E. coli* genome. The *E. coli* genome contains 4,289 encoded proteins).

In regard to claim 3, Bruccoleri teaches the selected pathogenic organism that includes at least *M. turberculosis* (page 4483, Table 3).

In regard to claim 4, Bruccoleri teaches the *M. turberculosis* genome at Table 3, therefore, it inherently comprises the DNA gyrase subunit of SEQ ID NO: 67 (**VRKRPGMYIG**) (as seen in GenBANK Accession number YP 001285950; amino acids 65-74).

In regard to claim 6, Bruccoleri teaches the *M. turberculosis* genome at Table 3, therefore, it inherently comprises DNA gyrase subunit B, as noted above.

In regard to claim 7, Bruccoleri teaches selecting organism names from a menu (page 4483, Table 2).

In regard to claim 8, Bruccoleri teaches selecting protein sequences and labeling them with an id number, a location and a name (page Table 3 and Table 4).

In regard to claim 9, Bruccoleri teaches determining overlapping sequences (CLUSTALW; page 4483, col. 2).

As Bruccoleri anticipates each of claims 1-4 and 6-9, no claims are allowed.

Response to Applicant's Arguments/Declaration filed under 37 CFR 1.132

1. Applicant argues that which is set forth in the Declaration under 37 CFR 1.132 filed 3 December 2008. Each argument will be addressed below.

Declaration

1. The Declaration under 37 CFR 1.132 by inventor Debasis Dash has been considered and is not deemed persuasive for the following reasons:

A. Applicant asserts that "the software used to perform the protocols disclosed in the present application and the cited reference is different".

This is not persuasive to overcome the art of record. As there is no software recited in the instant claims, the prior art of record performs the same method and therefore anticipates each of said claims. Applicant is reminded that although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

B. Applicant asserts that "the unique end result disclosed in the instant application can be achieved in half the number of steps as compared to the citation".

This is not persuasive to overcome the prior art of record. The instant claims do not preclude the use of other method steps to perform said invention. The steps of the method "comprise" the steps of computationally generating overlapping peptide sequences of length N from pathogenic organisms; sorting the peptide sequences to produce matched common peptides; locating matched common peptide sequences in their corresponding protein sequences to gather location and labeling origin and location; joining overlapping common sequences; and comparing extended conserved sequences to a host organism protein sequence to identify which of the conserved peptides are not present in the host. Each of said method steps is taught in the prior art of record and thus the prior art teaches that which is claimed. Because there is no structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the method, then it meets the claim.

C. Applicant argues states that "even short peptide sequences of protein can be traced with the disclosed technique, the minimum sensitivity being 4 amino acids and the maximum being any number. However, no details related to the application of their technique to the short peptide sequences or the sensitivity of the process is disclosed in their citation".

This is not persuasive to overcome the prior art. Bruccoleri et al. teach exactly the steps of identification of overlapping sequences (which would reasonably be peptides, given they are not complete sequences) and identifying potential drug targets. As peptides consist of two to several hundred amino acids, as is commonly known in the art, Bruccoleri et al. fairly teach

peptides. Further, the instant claims do not require that the peptide sequences consist only of 4 amino acids. In fact, the peptides listed in claim 4, for example, contain 13 amino acids (SEQ ID NO:1), 9 amino acids (SEQ ID NO:2), 15 amino acids (SEQ ID NO:60) etc... Therefore, the features for which Applicant relies upon are not claimed and although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

D. Applicant states that "in the present application, the target sites are identified at the end of the process and no knowledge of the target sites is needed at the beginning of the process" as opposed to the reference of Bruccoleri et al. Applicant states that "from the citation page number 4483, column 1, paragraph 3, it is understood that a Target genome has to be specified at the beginning itself".

This is not persuasive to overcome the prior art of record. The purpose of the method of Bruccoleri et al. is to identify the set of proteins which are conserved across microbes to identify targets of new anti-microbial agents. Bruccoleri et al. determine concordances of putative gene products that show sets of proteins conserved across one set of user specified genomes and not present in another set of user specified genomes. The instant claims encompass the same limitations with respect to genomes. The instant claims encompass generating overlapping peptide sequences of length N from **selected pathogenic organisms**. Therefore, the genome is known because the selection is from known pathogenic organisms. Further, those sequences, from a genome that is known, are compared to host sequences which are also known. Applicant's arguments are directed to the target genome information being known or not known.

In both the case of the reference and the instant claims, the genomes are known ahead of time. It is from this that a particular target may be identified.

E. Applicant asserts that "the nomenclature of the proteins tested in the present application is the same as that of the international database. A person of ordinary skill in the art seeking to perform this technique [over an unknown protein] can do so with the details disclosed in the present application. In contrast, the names of the sequences disclosed in the cited document (table 4) will not allow collection of the details of the desired sequence from the public domain, thus the methods of the citation can only be performed after collecting the details from the authors of the citation".

This is not persuasive to overcome the prior art of record. Firstly, the claims are not drawn to any particular protein with any particular international nomenclature, therefore the argument is not persuasive. Applicant is relying upon limitations which are not present in the instant claims. As reminded above, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Secondly, Bruccoleri et al., in Table 4, disclose results of a sample concordance in which several protein and peptide sequences are named, along with annotations for the named proteins and peptides. The gene names and their annotations are taken directly from GenBank deposition of the genome, as stated on page 4485, description of Table 4. Therefore, the gene names are readily accessible via a world wide database known as GenBank from which nomenclature is standard and for which all sequences are readily available to the public.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

December 24, 2008
/Lori A. Clow/
Primary Examiner, Art Unit 1631